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| 09/993,844      | 11/05/2001  | Robert H. Oakley     | 033072-026          | 8005             |

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EXAMINER

ULM, JOHN D

ART UNIT PAPER NUMBER

1646

DATE MAILED: 12/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/993,844

Applicant(s)

OAKLEY ET AL.

Examiner

John D. Ulm

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 31-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 November 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(a) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 5) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

- 1) Claims 1 to 37 are pending in the instant application.
- 2) Claims 31 to 37 are withdrawn from further consideration pursuant to 37

CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the correspondence filed 22 October of 2003.

3) The instant specification has been amended as requested by Applicant in the preliminary amendment that was filed on 05 November of 2001.

4) This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821 through 1.825. Specifically, no sequence listing has been provided which includes the amino acid sequence presented as "NPXXY" the instant specification and claims. Applicant needs to provide a substitute computer readable form (CRF) copy of a "Sequence Listing" which includes all of the sequences that are present in the instant application and encompassed by these rules, a substitute paper copy of that "Sequence Listing", an amendment directing the entry of that paper copy into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. §§ 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). The instant specification will also need to be amended so that it complies with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in

the specification and claims wherever a reference is made to that sequence. For rules interpretation Applicant may call (703) 308-1123. See M.P.E.P. 2422.04.

5) The instant specification does not comply with 37 C.F.R. § 1.84(U)(1), which states that partial views of a drawing which are intended to form one complete view, whether contained on one or several sheets, must be identified by the same number followed by a capital letter. Figure 8 of the instant application, for example, is presented on two separate panels. The two sheets of drawings which are labeled "Figure 8" in the instant specification should be renumbered "Figures 8A and 8B". Alternatively, the three drawings presented on those two sheets can be numbered "Figure 8A, 8B and 8C". Applicant is reminded that once Figures 8, 10 and 11 are changed to meet the separate numbering requirement of 37 C.F.R. § 1.84(U)(1), Applicant is required to file an amendment to change the Brief Description of the Drawings and the rest of the specification where necessary.

6) This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

7) The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because it was not executed in accordance with either 37 CFR 1.66 or 1.68. Specifically, it has not been signed by Stephane A. Laporte.

8) Claims 16 to 19 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A properly dependent claim can not conceivably be infringed without infringing any of the claims from which it depends. Claims 16 to 19 can be infringed by an isolated nucleic acid that does not infringe the GPCR protein of claim 1, from which they depend. See M.P.E.P. 608.01(n)III.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9) Claim 17 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A "nucleic acid sequence" is a property of a nucleic acid and not a material entity in and of itself. Therefore, a "sequence" is not subject to patentability any more than other properties such as size, shape and color.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10) Claims 1 to 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10.1) Claims 1 to 30 are vague and indefinite in so far as they employ the term "modified GPCR" as a limitation in the absence of appoint of reference. In order for an

item to be "modified" it must be altered from a previous form. Therefore, an unambiguous application of the limitation "modified" requires the identification of the original, unmodified item and the nature of the change or changes made thereto. This issue is particularly relevant to claim 15, in which it is unclear how the presence of the limitation "modified GPCR" distinguishes the claimed subject matter recited therein from an otherwise identical claim lacking that limitation.

10.2) Claim 1 is confusing because it recites structural features that are required to be present in a "second GPCR" from which a "portion of a carboxyl-terminus" is to be included in the "modified GPCR" of the claim, without indicating whether those structural features are supposed to be included in that "portion of a carboxyl-terminus" or in the "modified GPCR". This claim is further confusing because it appears to require the second GPCR to contain two putative sites of palmitoylation and two NPXXY motifs. The limitations "second putative site of palmitoylation" and "second NPXXY motif" have no antecedent basis in the claim because they are referring to "the second GPCR", which is not required to have a first putative site of palmitoylation or a first NPXXY motif. Claims 21 and 26 are confusing for essentially the same reasons. Claims 2 to 19, 22 to 25 and 27 to 30 are vague and indefinite in so far as they depend from any one of claims 1, 21 or 26 for these elements.

10.3) Claims 1 to 19, 21 and 23 are vague and indefinite in their recitation of the limitations "approximately 10 to 25 amino acids", "approximately 20 to 55 amino acids" and "approximately 30 to 45 amino acids". Even though the use of the term "approximately" in a claim is inherently vague and indefinite, its use is appropriate

when employed to limit a value which is composed of infinitely divisible units such as inches, meters, grams and pints where it is impractical to produce an item which has exactly the dimension recited. Even if one could practically produce an item that is exactly 1 inch in length, the length of that item is conditional upon the temperature at which it is measured. However, when defining an invention in terms of indivisible numerical units such as the number of nucleotides in a nucleic acid, the number of amino acids in a polypeptide or the number of legs on a chair or table, the term "approximately" is unacceptably vague and indefinite since it is practical to employ a term which possesses the required precision. If, for example, it is Applicant's intention that the claims should encompass a polypeptide of no more than 32 amino acids in length then this is exactly what the claim should recite. Whereas one would reasonably interpret the term "about one inch" as encompassing any value from 0.90 inches to 1.10 inches one would not know if the term "approximately 10 to 25 amino acids" would include or exclude 9, 8, or even 7 amino acids.

10.4) Claims 18 is vague and indefinite because there is no antecedent basis for "the nucleic acid of claim 17", which is drawn to a "sequence".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyster can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



JOHN ULM  
PRIMARY EXAMINER  
GROUP 1800